Office Action of the corresponding Chinese application

THE PATENT OFFICE OF THE PEOPLE'S REPUBLIC OF CHINA

Address: 6 Xi Tu Cheng Lu, Haidian, Beijing Post Code: 100088

Applicant:	ANGES MG, INC.	Date of Notification: Date: 20 Month: 06 Year: 2003
Attorney:	CHEN WENPING	
Application No.:	96197349.8	
Title of the Invention:	MEDICAMENT COMPRISING HGF GENE	

Notification of the First Office Action
(PCT Application in the National Phase)

1. ☒The applicant requested examination as to substance and examination has been carried out on the above-identified patent application for invention under Article 35(1) of the Patent Law of the People's Republic of China (hereinafter referred to as "the Patent Law").
   ☐ The Chinese Patent Office has decided to examine the application on its own initiative under Article 35(2) of the Patent Law.

2. ☒ The applicant claimed priority/priorities based on the application(s):
   filed in JP on Aug.29, 1995, filed in _____ on _____,
   filed in _____ on _____, filed in _____ on _____.

3. ☐ The following amendments submitted by the applicant are not acceptable under Art. 33 of the Patent Law:
   ☐ The Chinese translation of the amendments annexed to the IPEA Report.
   ☐ The Chinese translation of the amendments made under Art. 19 of PCT.
   ☐ The amendments made under Art. 28 or Art. 41 of PCT.
   ☐ The amendments made under Rule 51 of the Implementing Regulations of the Patent Law.
   Specific reasons why the amendments are not acceptable are set forth in the text portion of this Notification.

4. ☒Examination was directed to the Chinese translation of the International Application as originally filed.
   ☐ Examination was directed to the application documents as specified below:
   ☐ Description ☐ Pages _____of the Chinese translation of the International Application as originally filed.
   ☐ Pages _____of the Chinese translation of the amendments annexed to the IPEA Report.
   ☐ Pages _____of the amendments made under Art. 28 or Art. 41 of PCT.
   ☐ Pages _____of the amendments made under Rule 51 of the Implementing Regulations of the Patent Law.
   ☐Claims ☐ The Chinese translation of claims _____of the International Application as originally filed.
   ☐ The Chinese translation of claims _____of the amendments made under Art. 19 of PCT.
   ☐ The Chinese translation of claims _____of the amendments annexed to the IPEA Report.
   ☐ The Chinese translation of claims _____of the amendments made under Art. 28 or Art. 41 of PCT.
   ☐ The amendments of the claims _____made under Rule 51 of the Implementing Regulations of the Patent Law.
   ☐Drawings ☐ Pages _____of the Chinese translation of the International Application as originally filed.
   ☐ Pages _____of the Chinese translation of the amendments annexed to the IPEA Report.
   ☐ Pages _____of the amendments made under Art. 28 or Art. 41 of PCT.
   ☐ Pages _____of the amendments made under Rule 51 of the Implementing Regulations of the Patent Law.

5. ☒ Below is/are the reference(s) cited in this Office Action (the reference number(s) will be used throughout the examination procedure):

No.	Number(s) or Title(s) of Reference(s)	Date of Publication (or the filing date of conflicting application)
1	HEPATOLOGY, 19(4):962-72	Date: __ Month: __Year: 1994
2	J BIOL CHEM, 266(6):3361-4	Date: __ Month: __Year: 1991
3		Date: __ Month: __Year: ____
4		Date: __ Month: __Year: ____
5		Date: __ Month: __Year: ____

6. Conclusions of the Action:
   - ☐ On the Specification:
     - ☐ The subject matter contained in the application is not patentable under Article 5 of the Patent Law.
     - ☐ The description does not comply with Article 26 paragraph 3 of the Patent Law.
     - ☐ The draft of the description does not comply with Rule 18 of the Implementing Regulations.
   - ☒ On the Claims:
     - ☐ Claim(s) _____ is/are not patentable under Article 25 of the Patent Law.
     - ☐ Claim(s) _____ does/do not comply with the definition of inventions prescribed by Rule 2 paragraph 1 of the Implementing Regulations.
     - ☐ Claim(s) _____ does/do not possess the novelty as required by Article 22 paragraph 2 of the Patent Law.
     - ☒ Claim(s) 1-4 does/do not possess the inventiveness as required by Article 22 paragraph 3 of the Patent Law.
     - ☐ Claim(s) _____ does/do not possess the practical applicability as required by Article 22 paragraph 4 of the Patent Law.
     - ☐ Claim(s) _____ does/do not comply with Article 26 paragraph 4 of the Patent Law.
     - ☐ Claim(s) _____ does/do not comply with Article 31 paragraph 1 of the Patent Law.
     - ☒ Claim(s) 5-6 does/do not comply with the provisions of Rules 20-23 of the Implementing Regulations.
     - ☐ Claim(s) _____ does/do not comply with Article 9 of the Patent Law.
     - ☐ Claim(s) _____ does/do not comply with the provisions of Rule 12 paragraph 1 of the Implementing Regulations.

   The explanations to the above conclusions are set forth in the text portion of this Notification.

7. In view of the conclusions set forth above, the Examiner is of the opinion that:
   - ☐ The applicant should make amendments as directed in the text portion of the Notification.
   - ☐ The applicant should expound in the response reasons why the application is patentable and make amendments to the application where there are deficiencies as pointed out in the text portion of the Notification, otherwise, the application will not be allowed.
   - ☒ The application contains no allowable invention, and therefore, if the applicant fails to submit sufficient reasons to prove that the application does have merits, it will be rejected.
   - ☐ _____

8. The followings should be taken into consideration by the applicant in making the response:
   (1) Under Article 37 of the Patent Law, the applicant should respond to the office action within 4 months counting from the date of receipt of the Notification. If, without any justified reason, the time limit is not met, the application shall be deemed to have been withdrawn.
   (2) Any amendments to the application should be in conformity with the provisions of Article 33 of the Patent Law. Substitution pages should be in duplicate and the format of the substitution should be in conformity with the relevant provision contained in "The Examination Guidelines".
   (3) The response to the Notification and/or revision of the application should be mailed to or handed over to the "Reception Division" of the Patent Office, and documents not mailed or handed over to the Reception Divisions have no legal effect.
   (4) Without an appointment, the applicant and/or his agent shall not interview with the Examiner in the Patent Office.

9. This Notification contains a text portion of 2 pages and the following attachments:
   - ☒ 2 cited reference(s), totaling 2 pages. ☐

Examination Dept. _____ Examiner: Sun, Guangxiu Seal of the Examination Department

Chinese Patent Application No. 96197349.8

Text Portion of the Notification of the First Office Action

1. Claim 1 seeks to protect a medicament comprising HGF gene. The cited reference 1 (D1, Hepatology, 1994, 19(4):962-72, see the abstract) discloses that the liver repair of HGF-transgenic mice can be increased. In view of the pharmacological activity of HGF gene disclosed in D1, it is obvious for the person skilled in the art to useHGF gene as an active component of a medicament. Hence, claim 1 does not possess the inventiveness as required by Article 22(3) of the Patent Law.

2. Claim 2 seeks to protect a liposome containing a HGF gene. The cited reference 2 (D2, J Biol Chem, 1991, 266(6):3361-4, see the abstract) discloses a process for encapsulating heptatitis B virus surface antigen gene in liposomes and introducing it into cells by HVJ (hemagglutinating virus of Japan)-mediated membrane fusion to express exogenous protein in the cells. It is obvious for the person skilled in the art to encapsulate therapeutic HGF gene into a liposome to use as a medicament of gene treatment on the basis of D1 and D2. Hence, the content of claim 2 is obvious, and does not possess the inventiveness as required by Article 22(3) of the Patent Law.

3. Claim 3 defines the liposome in claim 2 as a membrane fusion liposome fused to Sendai virus, which has been disclosed in D1. Therefore, in view of claim 2 does not possess inventiveness, claim 3 does not possess the inventiveness as required by Article 22(3) of the Patent Law, either.

4. Claim 4 seeks to protect a medicament comprising a liposome according to claim 2 or 3. In view of the disclosures of D1 and D2, for the same reason above-mentioned, claim 4 does not possess the inventiveness as required by Article 22(3) of the Patent Law, either.

5. The subject matter of claims 5 and 6 is a medicament, but their characterizing portion is the use of said medicament, which renders claims 5 and 6 unclear, and thus do not comply with Rule 20(1) of the Implementing Regulations of the Patent Law. Even if the applicant amend claims 5 and 6 into

use claims to overcome the above defect, claims 5 and 6 still do not possess the inventiveness as required by Article 22(3) of the Patent Law. Firstly, the medicament in claims 5 and 6 does not possess inventiveness, and secondly, HGF protein can be used in the treatment for arterial diseases and cartilage injury according to the disclosures contained in the description. Well then, it is obvious that the HGF gene after expression by introducing it into body with transgenic technique has same pharmacological activity as HGF protein, i.e., it is obvious that HGF gene potentially has the use for treating arterial diseases and cartilage injury.

In sum, all claims in the present application are not allowable. Moreover, even if the applicant limits the protection scopes of the claims according to the content disclosed in the examples, said claims still do not possess inventiveness over the disclosures of D1 and D2 (see the reason in above paragraphs). That is to say, the description also contains no allowable substantive content. If the applicant fails to submit sufficient reasons to prove that the application does have patentability within the time limit specified in the Notification, it will be rejected.

Reference cited in the Office Action of the corresponding Chinese application (D2)

J Biol Chem 1991 Feb 25;266(6):3361-4

Related Articles, Links

Free full text article at www.jbc.org

Expression of hepatitis B virus surface antigen in adult rat liver. Co-introduction of DNA and nuclear protein by a simplified liposome method.

Kato K, Nakanishi M, Kaneda Y, Uchida T, Okada Y.

Institute for Molecular and Cellular Biology, Osaka University, Japan.

We established a simple and efficient method for gene transfer in vitro (to cultured cells) and in vivo (to an adult organ) using liposomes. Plasmid DNA and proteins were efficiently co-encapsulated in liposomes by agitation and sonication, and were co-introduced into cells by hemagglutinating virus of Japan (HVJ)-mediated membrane fusion. Introduction of the Escherichia coli beta-galactosidase gene with non-histone chromosomal protein high mobility group 1 (HMG1) into LLCMK2 cells resulted in about 3 times higher beta-galactosidase activity than that on introduction of the gene alone. Two days after injection of HVJ-liposomes containing the beta-galactosidase gene and HMG1 under the perisplanchnic membrane of adult rat liver, hepatic cells near the injection site were found by 5-bromo-4-chloro-3-indolyl beta-D-galactoside staining to have beta-galactosidase activity. After similar injection of HVJ-liposomes containing the hepatitis B virus surface antigen (HBsAg) gene and HMG1, HBsAg was detected in the serum for 9 days with a maximum of 25-45 ng/ml on day 2 after the injection.

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